AUG - 5 2011

510(k) Summary
510(k) Number K101517

Sedecal, Inc.
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Date Prepared: May 27, 2010
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: Sedecal Mobile Digital Diagnostic X-Ray Systems (various models)
   Classification Name: Mobile x-ray system, Product Code IZL and Solid State X-Ray Imager (Flat Panel/Digital Imager) MQB, with Image Processing Software Code LLZ.
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2. **Equivalent legally marketed devices:** K090322 Easy Moving Plus Mobile X-Ray, and K091364, DICOMPACS, MODEL 5.2, DICOMPACS DX-R, MODEL 1.4, OEHM UND REHBEIN GMBH

3. **Indications for Use (intended use)** Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. **Description of the Device:** Sedecal Digital Mobiles (various models) are mobile x-ray units that covers, with a range of models, all the specific needs of any radiographic examination at the patient's bed, first aid, and emergency, orthopedics, pediatric, and operating theater. These cordless units combine stand alone feature for exposures with battery assisted motor drive for the greatest ease in imaging. Two different brands of digital image acquisition panels are offered: Trixell and Varian. Integrated software for Dicom compatibility is also included. Model list:
   For Varian: SM-20HF-B-D-V, SM-32HF-B-D-V, SM-40HF-B-D-V, SM-50HF-B-D-V.
   For Trixell: SM-20HF-B-D-T, SM-32HF-B-D-T, SM-40HF-B-D-T, SM-50HF-B-D-T.
   The numeric value indicates the generator power in kW. All units are supplied with Dicom software. (K091364)

5. **Safety and Effectiveness, comparison to predicate device.** Bench, test laboratory results, and clinical image comparisons indicate that the new devices are as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart**

Characteristic	Sedecal Easy Moving Digital K090322	Sedecal Mobile Digital Diagnostic X-Ray Systems (various models)
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME
Configuration	Battery or line operated mobile	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Generator power levels	20 to 50 kw (4 models)	20 to 50 kw (8 models)
Collimator	Ralco R221 DHHS	SAME
Image acquisition	Digital CANON 50G	Trixell or Varian
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. **Conclusion**

After analyzing bench, laboratory, and clinical testing to applicable standards, it is the conclusion of Sedecal Inc that the modified Sedecal Mobile X-Ray Systems are as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2013

SEDECAL SA
% Mr. Danial Kamm, P.E.
Regulatory Engineer, Submission Correspondent
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K101517
Trade/Device Name: Sedecal Mobile Digital Diagnostic X-Ray Systems (various models)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL and MQB
Dated: June 15, 2011
Received: June 17, 2011

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of August 9, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101517

Device Name: Sedecal Mobile Digital Diagnostic X-Ray Systems (various models)

Indications For Use:
These Digital Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-vitro Diagnostics (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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